General

Guideline Title

HIV prophylaxis following occupational exposure.

Bibliographic Source(s)

New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2012 Oct. 39 p. [39 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2010 May. 59 p. [19 references]

Recommendations

Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

What's New – October 2012 Update

Significant revisions include the following:

- The Medical Care Criteria Committee now recommends tenofovir + emtricitabine (lamivudine may be substituted for emtricitabine) plus raltegravir as the preferred initial post-exposure prophylaxis (PEP) regimen because of its excellent tolerability, proven potency in established human immunodeficiency virus (HIV) infection, and ease of administration. Zidovudine is no longer recommended in the preferred PEP regimen because it is believed to have no clear advantage in efficacy over tenofovir while having significantly higher rates of treatment-limiting side effects.
- Occupational exposures require urgent medical evaluation. In this update, the Committee further emphasizes recommendations regarding the importance of initiating occupational PEP as soon as possible, ideally within 2 hours of exposure. A first dose of PEP should be offered while evaluation is underway. PEP should not be delayed while awaiting information about the source patient or results of the exposed worker's baseline HIV test.
- This update incorporates amendments to New York State regulations (10 NYCRR part 63) regarding testing of source patients and access to HIV-related information after occupational exposures (see Appendix C in the original guideline document).
- If the source patient's rapid HIV test result is negative but there has been a risk for HIV exposure in the previous 6 weeks, plasma HIV

ribonucleic acid (RNA) testing of the source patient is also recommended. In this situation, PEP should be initiated and continued until results of the plasma HIV RNA assay are available.
- A recommendation has been added that baseline HIV testing of the exposed worker should always be obtained after an occupational exposure, even if the exposed worker declines PEP.
- Recommendations for follow-up HIV testing of the exposed worker have been changed. Regardless of whether the exposed worker accepts or declines PEP treatment, if the post-exposure evaluation determines that PEP is indicated, repeat HIV testing at 4 weeks and 12 weeks should be obtained. A negative HIV test result at 12 weeks post-exposure reasonably excludes HIV infection related to the occupational exposure; routine testing at 6 months post-exposure is no longer recommended.
- Appendix B of the original guideline document includes an updated comparison of occupational PEP recommendations from the New York State Department of Health AIDS Institute and the Centers for Disease Control and Prevention.

Rationale for PEP

The Committee recommends the use of a three-drug PEP regimen for all significant risk exposures.

Responsibilities for Employers

As part of a comprehensive plan to prevent the transmission of bloodborne pathogens, employers should implement the use of safety devices and educate workers about how to prevent needlestick injuries. (AIII)

Antiretroviral medications for PEP should be readily available to exposed workers who sustain a potential occupational exposure to HIV. (AIII) When establishing plans for providing PEP, employers should determine the following:

- Who will perform the post-exposure evaluation
- Who will provide counseling to the exposed worker regarding the exposure and indications for PEP (for off-hour exposures as well)
- How PEP will be made available within 2 hours of an exposure
- How a 3- to 5-day supply of PEP will be made available for urgent use
- Who will be given authority for releasing drugs for this purpose
- How the exposed worker will obtain a continuous supply of PEP drugs to complete the 28-day regimen

Employers should determine who will pay for PEP and establish policies for submitting claims to their Workers' Compensation plan. Exposed workers should not be expected to pay out-of-pocket for PEP, even if it is reimbursed at a later date.

Post-Exposure Management and Evaluation

Occupational PEP should be initiated as soon as possible, ideally within 2 hours of the exposure. A first dose of PEP should be offered to the exposed worker while the evaluation is underway. (AII)

Management of the Exposed Site

Body sites exposed to potentially infectious fluid should be cleansed immediately. Wound and skin exposure sites should be washed with soap and water. Exposed mucous membranes should be flushed with water. The exposed worker should not attempt to "milk" the wound. (AII)

Evaluating the Exposure

Prompt initiation of PEP is recommended for exposure to blood, visibly bloody fluids, or other potentially infectious material (semen; vaginal secretions; breast milk; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) from HIV-infected or HIV-unknown sources in any of the significant exposure situations outlined in the Table below. (AII)

Initiation of PEP should be followed by telephone or in-person consultation with a clinician experienced in HIV PEP. Clinicians who do not have access to experienced HIV clinicians should call the National Clinicians' Consultation Center PEP Line at 1-888-448-4911. When using the PEP Line, providers from New York State should identify themselves as such.

Table: Exposures For Which PEP Is Indicated

- Break in the skin by a sharp object (including hollow-bore, solid-bore, and cutting needles or broken glassware) that is contaminated with blood, visibly bloody fluid, or other potentially infectious material, or that has been in the source patient's blood vessel
- Bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed worker
- Splash of blood, visibly bloody fluid, or other potentially infectious material to a mucosal surface (mouth, nose, or eyes)

Table: Exposures For Which PEP Is Indicated

- A non-intact skin (e.g., dermatitis, chapped skin, abrasion, or open wound) exposure to blood, visibly bloody fluid, or other potentially infectious material

HIV Testing of the Source Patient

If the HIV serostatus of the source patient is unknown, consent for voluntary HIV testing of the source patient should be sought as soon as possible after the exposure. (AII) Rapid HIV testing is strongly recommended for the source patient. Organizations subject to Occupational Safety and Health Administration (OSHA) regulations are required to perform rapid HIV testing rather than standard HIV testing. (AIII)

In New York State, when the source patient has the capacity to consent to HIV testing, specific informed consent is required; if consent is not obtained, HIV testing cannot be performed. When the source person does not have the capacity to consent, consent may be obtained from a surrogate, or anonymous testing may be done if a surrogate is not readily available. See Appendix C in the original guideline document for information regarding HIV testing when the source patient does not have the capacity to consent. Clinicians should follow individual institutional policies for obtaining consent.

If the source patient consents to HIV testing and the rapid HIV test is positive, this preliminary result should be utilized in decision-making regarding PEP for the exposed worker. The preliminary positive result should be provided to the source patient and followed by confirmatory testing as soon as possible. (AIII) (When anonymous testing is performed, the results of the test cannot be disclosed to the source person or placed in the source person's medical record; see Appendix C in the original guideline document.)

If the source patient's rapid HIV test result is negative but there may have been exposure to HIV in the previous 6 weeks, a plasma HIV RNA assay should also be obtained. (BIII) In these situations, PEP should be continued until results of the plasma HIV RNA assay are available. (BIII)

If the result from testing the source patient is not immediately available or a complete evaluation of the exposure is unable to be made within 2 hours of the exposure, PEP should be initiated while source testing and further evaluation are underway. (AII)

Recording Information Following Occupational Exposure

When an occupational exposure occurs, the following information should be recorded in the exposed worker's confidential medical record:

- Date and time of the exposure
- Details of the procedure being performed and the use of protective equipment at the time of the exposure
- The type, severity, and amount of fluid to which the worker was exposed
- Details about the source patient
- Whether consent was obtained for HIV testing of the source patient
- Medical documentation that provides details about post-exposure management

If the exposed worker declines PEP, this decision should be documented in the worker's medical record.

Specific Occupational Safety and Health Administration (OSHA) requirements regarding documentation may be found at Safety and Health Topics: Bloodborne Pathogens and Needlestick Prevention.

Baseline Testing for the Exposed Worker

Confidential baseline HIV testing of the exposed worker should be obtained at the time the occupational exposure is reported or within 3 days of the exposure. (AIII) Testing must be performed in full compliance with New York State Public Health Law.

PEP should be started without waiting for the results of the HIV test. (AII)

Key Point:

A negative HIV test only demonstrates that the exposed worker was not previously infected with HIV before the exposure occurred; the baseline HIV test *cannot* determine whether the exposed worker was infected as a result of the exposure.

Timing of Initiation of PEP

When a potential occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours.

(AII) A first dose of PEP should be offered to the exposed worker while the evaluation is underway.

Decisions regarding initiation of PEP beyond 36 hours post-exposure should be made on a case-by-case basis with the realization of diminished efficacy when timing of initiation is prolonged. (AII)

An absolute elapsed time after which PEP should not be administered cannot be stated with certainty.

Recommended PEP Regimen

The preferred PEP regimen is tenofovir + emtricitabine (lamivudine may be substituted for emtricitabine) plus raltegravir (see the table below for dosing and Appendix A of the original guideline document for description of each drug). Zidovudine is no longer recommended in the preferred PEP regimen. The first dose should be given as soon as possible after exposure, ideally within 2 hours. The recommended duration of PEP is 28 days.

Table: Recommended Regimen for HIV PEP Following Occupational Exposure[a]
Tenofovir[b] 300 mg orally (PO) once a day (qd) + Emtricitabine[b,c] 200 mg PO qd Plus Raltegravir[d] 400 mg PO twice a day (bid)
[a] When the source is known to be HIV-infected, past and current antiretroviral therapy (ART) experience, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen. Consult with a clinician experienced in managing PEP. [b] The dosing of tenofovir and emtricitabine/lamivudine should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A in the original guideline document for dosing recommendations). Tenofovir should be used with caution in exposed workers with renal insufficiency or who are taking concomitant nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure. [c] Lamivudine 300 mg PO qd may be substituted for emtricitabine. However, a fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 PO qd). [d] The dosing of raltegravir should be adjusted when co-administered with rifampin (see Appendix A in the original guideline document for dosing recommendations).

If the source patient is known to be HIV-infected and information is immediately available regarding past and present antiretroviral therapy (ART) experience, current level of viral suppression, or resistance profile, the treating clinician, in consultation with a clinician experienced in managing PEP, should individualize the PEP regimen to maximize potential effectiveness against the exposed HIV strain. (AII) Initiation of the first dose and continuation of PEP should never be delayed while awaiting this information. (AII) If indicated, the regimen can be changed when more information becomes available.

The tables below list recommended alternative PEP regimens that should be used in the setting of potential HIV resistance, toxicity risks, clinician preference, or constraints on the availability of particular agents. (AII)

Clinicians should switch exposed workers to an alternative regimen if the initial or subsequent PEP regimen is not well tolerated (see Appendix A in the original guideline document for potential adverse events).

Treating clinicians should consult with a clinician experienced in managing PEP when alternative agents are prescribed or if there is doubt as to whether PEP should be continued after the first dose.

The prescribing clinician should ensure that the exposed worker has access to the full 28-day recommended course of antiretroviral medications (AIII) and is appropriately monitored for toxicities during the treatment (see "Responsibilities of Employers" section above and "Follow-Up and Monitoring of the Exposed Worker Following Occupational Exposure" section below).

Treating clinicians who do not have access to experienced HIV clinicians should call the National Clinicians' Consultation Center PEP Line at

1-888-448-4911. When using the PEP Line, providers from New York State should identify themselves as such.

Duration of PEP Regimen

When the source patient is confirmed to be HIV-negative, clinicians should discontinue the PEP regimen before completion (see "HIV Testing of the Source Patient" above).

If the exposed worker's baseline test shows evidence of HIV infection acquired before the exposure and initiation of PEP, decisions regarding continuation of ART should be based on current treatment guidelines (see the National Guideline Clearinghouse [NGC] summary of the New York State Department of Health [NYSDOH] guideline Antiretroviral Therapy). However, the PEP regimen should not be discontinued until the positive result is repeated with a confirmatory assay.

If the exposed worker's week 4 post-exposure HIV test results are indeterminate or the exposed worker has symptoms suggestive of acute HIV infection, clinicians should continue ART beyond 28 days until a definitive diagnosis is established.

Use of a Three-Drug PEP Regimen

Once a decision has been made that a significant risk exposure (see "Evaluating the Exposure" section above) has occurred and that PEP is warranted, this Committee recommends a three-drug regimen as the preferred option.

Preferred Alternative PEP Regimens

The preferred alternative PEP regimen is tenofovir + emtricitabine (lamivudine may be substituted for emtricitabine) plus ritonavir-boosted darunavir, atazanavir, or fosamprenavir (see the Table below).

Clinicians should carefully assess for potential drug interactions between these agents and other medications (including prescription medications and over-the-counter drugs, such as proton pump inhibitors and H2-blockers) that the patient may be taking. See Appendix A in the original guideline document for information regarding dosing, adverse effects, and drug interactions.

Clinicians should consult a clinician experienced in managing PEP or an occupational health clinician experienced in providing PEP when using alternative PEP regimens (AII). If consultation cannot be immediately obtained, the first dose of the regimen should be given rather than delaying initiation, with consultation occurring as soon as possible thereafter (AII). Clinicians who do not have access to experienced HIV clinicians should call the National Clinicians' Consultation Center PEP Line at 1-888-448-4911. When using the PEP Line, providers from New York State should identify themselves as such.

Table: Preferred Alternative PEP Regimens Following Occupational Exposure
Tenofovir[a] 300 mg PO qd + Emtricitabine[a,b] 200 mg PO qd Plus Darunavir 800 mg PO qd[c], or Atazanavir 300 mg PO qd[c], or Fosamprenavir 1400 mg PO qd[c] and Ritonavir 100 mg PO qd[c]
[a] The dosing of lamivudine/emtricitabine, and tenofovir should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A in the original guideline document for dosing recommendations). Tenofovir should be used with caution in exposed workers with renal insufficiency or who are taking concomitant nephrotoxic medications. Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure. [b] Lamivudine 300 mg PO qd may be substituted for emtricitabine. However, a fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 PO qd). [c] See Appendix A in the original guideline document for dosing recommendations for protease inhibitors in exposed workers with hepatic impairment.

Other Alternative PEP Regimens

Table: Alternative PEP Regimens Following Occupational Exposure[a]
• Tenofovir + Emtrictabine[b] + Zidovudine • Tenofovir + Emtricitabine[b] + Lopinavir/ritonavir • Zidovudine + Lamivudine[c] + one of the following ritonavir-boosted protease inhibitors: Darunavir, Atazanavir, Fosamprenavir, or Lopinavir
[a] See Appendix A in the original guideline document for full dosing information for alternative ARV agents that may be used in the PEP regimen. Also see the NYSDOH guideline HIV Drug-Drug Interactions for important drug interactions. Dosing interval of zidovudine should be adjusted in patients with baseline creatinine clearance <15 mL/min. The dosing interval of lamivudine, emtricitabine, and tenofovir should be adjusted in patients with baseline creatinine clearance <50 mL/min. (see Appendix A in the original guideline document for dosing recommendations in patients with renal impairment). Fixed-dose combinations should not be used in patients who need dose adjustment due to renal failure. [b] Lamivudine 300 mg PO qd may be substituted for emtricitabine. However, a fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 PO qd). [c] Emtricitabine 200 mg PO qd may be substituted for lamivudine. However, a fixed-dose combination is available when zidovudine is used with lamivudine (Combivir 1 PO qd).

Antiretroviral Drugs to Avoid as PEP Components

Consultation with a clinician experienced in managing PEP is recommended before using any of the following non-preferred antiretroviral drugs in a PEP regimen (see the section "PEP for Exposed Workers Who Are Pregnant or Breastfeeding" below for drugs to avoid in exposed workers who are pregnant or breastfeeding):

- Efavirenz
- Nevirapine
- Abacavir
- Stavudine and Didanosine
- Nelfinavir and Indinavir
- CCR5 co-receptor antagonists
- Rilpivirine and Etravirine

See the original guideline document for additional information.

Follow-Up and Monitoring of the Exposed Worker Following Occupational Exposure

All exposed workers receiving PEP should be re-evaluated within 3 days of the exposure. (AIII) This allows for further clarification of the nature of the exposure, review of available source patient data, and evaluation of adherence to and toxicities associated with the PEP regimen.

The exposed worker should be evaluated weekly while receiving PEP to assess treatment adherence, side effects of treatment, interval physical complaints, and emotional status. (AIII) Longitudinal care of the exposed worker during PEP treatment and the follow-up period should be provided by an occupational health provider familiar with PEP or directly by or in consultation with a clinician experienced in managing PEP. Providers who do not have access to a clinician experienced in PEP should use the National Clinicians' Consultation Center PEP line at 1-888-HIV-4911 (1-888-448-4911) for phone consultation. When using the PEP Line, providers from New York State should identify themselves as such.

Clinicians should provide risk-reduction counseling to HIV-exposed workers to prevent secondary transmission during the 12-week follow-up period. HIV-exposed workers should be advised to:

- Use condoms to prevent potential sexual transmission

- Avoid pregnancy and breastfeeding
- Avoid needle-sharing
- Refrain from donating blood, plasma, organs, tissue, or semen

Table: Monitoring Recommendations After Initiation of PEP Regimens Following Occupational Exposure[a]

	Baseline	Week 1	Week 2	Week 3	Week 4	Week 12
Clinic Visit	X	X or by telephone	X or by telephone	X or by telephone	X	
Pregnancy Test	X					
Serum liver enzymes, blood urea nitrogen (BUN), creatinine, complete blood cell count (CBC)[b]	X		X		X	
HIV test[c]	X				X	X

[a] For post-exposure management for hepatitis B and C, see Occupational Exposures to Hepatitis B and C section below.

[b] CBC should be obtained for all exposed workers at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.

[c] Recommended even if PEP is declined.

Sequential HIV Testing

Sequential confidential HIV testing should be obtained at baseline, week 4, and week 12 post-exposure:

- HIV testing at 6 months post-exposure is no longer recommended
- HIV testing of the exposed worker at 4 weeks and 12 weeks should be performed with laboratory-based HIV tests rather than rapid point-of-care HIV tests
- If the post-exposure evaluation determined that PEP was indicated, but the exposed worker declines PEP, serial testing should still be obtained (see the Table above)

If at any time the HIV test result is positive, a confirmatory assay must be performed to confirm the diagnosis of HIV infection.

If the exposed worker presents with signs or symptoms of acute HIV seroconversion, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay (AII) to diagnose acute HIV infection. A fourth-generation HIV antigen/antibody combination test is the preferred serologic screening test if available. Immediate consultation with a clinician experienced in managing ART should be sought for optimal treatment options.

PEP for Exposed Workers Who Are Pregnant or Breastfeeding

Exposed Workers Who Are Pregnant

Based on increasing clinical experience with ART, PEP is indicated at any time during pregnancy when a significant exposure has occurred, despite possible risk to the woman and the fetus. (AII) Expert consultation should be sought. When occupational exposure to HIV occurs, every effort should be made to initiate PEP within 2 hours. (AII) The recommended PEP regimen is the same for pregnant women as for non-pregnant adults (see the section "Recommended PEP Regimen" above). (AII)

Before administering PEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus.

Table: PEP Drugs To Avoid During Pregnancy	
Drug(s) to Avoid	Toxicity
Efavirenz	Teratogenicity
Combination of stavudine and didanosine	Mitochondrial toxicity
Nevirapine	Hepatotoxicity
Unboosted indinavir in the 2nd or 3rd trimester	Substantially lower antepartum indinavir plasma concentrations; risk for nephrolithiasis

Key Point:

In addition to the risk of seroconversion for the exposed worker, the high viral load levels associated with the acute retroviral syndrome markedly increase the risk of transmission to the fetus or breastfeeding infant.

Exposed Workers Who Are Breastfeeding

Clinicians should advise women who may have been exposed to HIV through occupational exposure to avoid breastfeeding for 3 months after the exposure. (AII) If HIV infection is definitively excluded in the source patient at any time prior to 3 months post-exposure, the woman may resume breastfeeding.

Occupational Exposures to Hepatitis B and C

When an occupational exposure occurs, the source patient should be evaluated for both hepatitis B and hepatitis C. (AII) (See Table 8 "Average Risk for Transmission of Hepatitis B and C Viruses after Needlestick [compared with HIV]" in the original guideline document).

Hepatitis B Virus (HBV) Post-Exposure Management

The hepatitis B vaccine series should be initiated in *non-HBV-immune* exposed workers who sustain a blood or body fluid exposure. (AI)

Determination of antibody response of previously vaccinated exposed workers should be based on information available at presentation. Decision-making should not be delayed while testing for antibody to hepatitis B surface antigen (anti-HBs) (see the table below).

Administration of prophylactic hepatitis B immune globulin (HBIG) and the initiation of the hepatitis B vaccine series injected at different sites are recommended when the non-HBV-immune exposed worker sustains a blood or body fluid exposure to a source patient with known acute or active HBV (see the table below). (AI) Both HBIG and the first dose of the hepatitis B vaccine series should be ideally administered within 24 hours of exposure (AII); HBIG should not be given later than 14 days post-exposure. The three-dose HBV vaccine series is given at 0, 1 to 2 months, and 6 months. Hepatitis B antibodies should be obtained 1 to 2 months after completion of the third dose of the vaccine.

Needlestick injuries and wounds should be washed with soap and water and should not be squeezed. Mucous membranes should be flushed with water. (AIII)

Table: Recommended Post-Exposure Prophylaxis for Hepatitis B Virus			
Vaccination and/or antibody response status of exposed person[a]	Treatment when source patient is:		
	HBsAg positive	HBsAg negative	Source unknown or not available for testing
Unvaccinated/non-immune	HBIG[b] x 1; initiate HBV vaccine series	Initiate HBV vaccine series	Initiate HBV vaccine series
Previously vaccinated[c], known responder[d]	No treatment	No treatment	No treatment

Table: Recommended Post-Exposure Prophylaxis for Hepatitis B Virus

Vaccination and/or antibody response status of exposed person[a]	Treatment when source patient is:		
	HBsAg positive	HBsAg negative	Source unknown or not available for testing
Previously vaccinated[c], antibody response unknown	Single vaccine booster dose	No treatment	No treatment unless known high-risk source; if high-risk source[f], then treat as if source were HBsAg positive
If still undergoing vaccination	HBIG[b] x 1; complete series	Complete series	Complete series

HBsAg, hepatitis B surface antigen; HBIG, hepatitis B immune globulin; anti-HBs, antibody to hepatitis B surface antigen.

[a]Persons who have previously been infected with HBV are immune to re-infection and do not require PEP.

[b] Dose 0.06 mL/kg intramuscularly

[c] Vaccinated with full three-dose series

[d] Based on information available at presentation. Responder is defined as person with previously documented adequate levels of serum antibody to HBsAg (serum anti-HBs ≥10mIU/mL); non-responder is a person with previously documented inadequate response to vaccination (serum anti HBs <10mIU/mL). It is not recommended that decision-making be delayed while testing for anti-HBs at presentation.

[e] The option of giving one dose HBIG and re-initiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

[f] High-risk is defined as sources who engage in needle-sharing or high-risk sexual behaviors, and those born in geographic areas with HBsAg prevalence of ≥2%.

Hepatitis C Virus (HCV) Post-Exposure Management

Clinicians should consider concurrent exposure to HCV when exposed workers present with an HIV exposure. (AII)

Neither immunoglobulin nor antiviral agents are recommended for HCV post-exposure prophylaxis.

When HCV infection is identified, the exposed worker should be referred for medical management to a clinician with experience in treating HCV. (AII)

Baseline Management

Following an exposure to blood or body fluid, the clinician should assess the risk for exposure to HCV. (AII) Wounds should be washed with soap and water, and should not be squeezed. (AII) Mucous membranes should be flushed with water.

Once the clinician has determined that exposure to blood or body fluid has occurred, the following baseline tests should be obtained (see the table below for follow-up according to baseline results):

Source Patient

- HCV antibody test (e.g., enzyme immunoassay/enzyme-linked immunosorbent assay [EIA/ELISA]), and if positive, HCV ribonucleic acid (RNA) test or recombinant immunoblot assay (RIBA)

Exposed Worker

- Liver panel including liver enzymes
- HCV antibody, and if positive, HCV RNA test

Table: Hepatitis C Post-Exposure Management According to Baseline Test Results	
Clinical Scenario	Follow-Up[a]
Source patient is HCV-antibody negative	No further testing or follow-up is necessary for source patient or the exposed worker[b]
Source patient is unavailable or refuses testing	Exposed worker: Follow-up HCV antibody at 3 and 6 months[b]
Source patient is HCV-antibody positive and HCV RNA negative	Manage the exposed worker as if the source patient has chronic hepatitis C (see Section *Post-Exposure Follow-Up for HCV*)[c]
Source patient is positive for both HCV antibody and HCV RNA *and* Exposed worker is HCV-antibody negative	Source patient: Counsel and manage as chronic hepatitis C regardless of status of exposed worker Exposed worker: Follow up as outlined in Section *Post-Exposure Follow-Up for HCV*
Exposed worker tests positive for both HCV antibody and HCV RNA	Counsel and manage as chronic hepatitis C
[a] Refer to Appendix E in the original guideline document for information about HCV tests and how to interpret results. [b] If at any time the serum alanine transaminase (ALT) level is elevated in the exposed worker, the clinician should test for HCV RNA to assess for acute HCV infection. [c] A single negative HCV RNA result does not exclude active infection.	

Clinicians should educate exposed workers about the natural history of HCV infection and should counsel exposed workers about the following:

- Avoidance of alcohol and, if possible, medications that may be toxic to the liver
- Risk of transmission related to:
  - Blood-to-blood contact, including sharing personal care items that may have come in contact with another person's blood, such as razors or toothbrushes; occupational needlestick injuries; and sharing needles, syringes, or other equipment to inject drugs
  - Sexual activity
  - Donating blood, plasma, organs, tissue, or semen
  - Perinatal transmission
- Hepatitis C virus is not spread via food or water and is not transmitted by:
  - Sharing eating utensils
  - Hugging, kissing, or holding hands
  - Coughing or sneezing
  - Breastfeeding: HCV is not transmitted by breastfeeding; however, clinicians should advise women who may have been exposed to HIV to avoid breastfeeding for 3 months after the exposure.

Post-Exposure Follow-Up for HCV

If the source patient is known to be positive for HCV antibody and/or HCV RNA, the follow-up schedule for the exposed worker should be as follows: (AII)

- Week 4: HCV RNA and liver panel
- Week 12: HCV RNA and liver panel
- Week 24: Liver panel and HCV antibody

If at any time the serum alanine transaminase (ALT) level is elevated, the clinician should repeat HCV RNA testing to confirm acute HCV infection. (AII)

At any time that exposed workers test positive for HCV RNA, the clinician should refer for medical management and possible treatment by a

clinician with experience in treating HCV. (AIII)

Definitions:

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

An algorithm is provided in the original guideline document for "Post-Exposure Prophylaxis (PEP) Following Occupational Exposure."

Scope

Disease/Condition(s)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus (HBV) infection
- Hepatitis C virus (HCV) infection

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Clinical Laboratory Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To provide guidelines for effective post-exposure prophylaxis of human immunodeficiency virus (HIV) and hepatitis B and C virus following occupational exposure in health care workers
- To update previously published guidelines on this topic

Target Population

Health care workers after possible occupational exposure to human immunodeficiency virus (HIV) or hepatitis B virus or hepatitis C virus

Interventions and Practices Considered

Management/Prevention of Occupational Exposure to Human Immunodeficiency Virus (HIV)

1. Use of safety devices to prevent the transmission of bloodborne pathogens and education of workers about how to prevent needlestick injuries
2. Ready availability of antiretroviral medications for post-exposure prophylaxis (PEP)
3. Establishment of policies for reimbursement for PEP and for submitting claims to Workers' Compensation plans
4. Initiating occupational PEP as soon as possible, ideally within 2 hours of the exposure
5. Cleansing of body sites exposed to potentially infectious fluid
6. Telephone or in-person consultation with a clinician experienced in HIV PEP after initiation of PEP
7. Obtaining consent for voluntary HIV testing of the source patient if the HIV serostatus of the source patient is unknown
8. Use of rapid HIV testing followed by confirmatory testing, if positive
9. Plasma HIV ribonucleic acid (RNA) assay when indicated
10. Recording information on occupational exposure in the exposed worker's confidential medical record
11. Confidential baseline HIV testing of the exposed worker at the time the occupational exposure
12. Preferred PEP regimen: tenofovir + emtricitabine (lamivudine may be substituted for emtricitabine) plus raltegravir
13. Alternative PEP regimens if the initial or subsequent PEP regimen is not well tolerated: e.g., tenofovir + emtricitabine (lamivudine may be substituted for emtricitabine) plus ritonavir-boosted darunavir, atazanavir, or fosamprenavir
14. Consulting with a clinician experienced in managing PEP
15. Duration of PEP regimen
16. Assessing for potential drug interactions
17. Follow-up and monitoring of the exposed worker following occupational exposure
18. Providing risk-reduction counseling to HIV-exposed workers to prevent secondary transmission during the 12-week follow-up period
19. Sequential confidential HIV testing should be obtained at baseline, week 4, and week 12 post-exposure
20. PEP for exposed workers who are pregnant or breastfeeding

Management of Occupational Exposure to Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)

1. Source patient evaluation for HBV and HCV

2. Initiation of hepatitis B vaccine series to workers with potential exposure to blood and body fluids
3. Administration of hepatitis B immune globulin (HBIG) and initiation of hepatitis B vaccine series if worker is exposed to a source patient with acute or active hepatitis B
4. Cleansing of needlestick injuries with soap and water
5. HCV antibody test (enzyme immunoassay/enzyme-linked immunosorbent assay [EIA/ELISA]), HCV RNA or recombinant immunoblot assay (RIBA) in the source patient
6. Liver panel including liver enzymes, HCV antibody, HCV RNA
7. Referral to a clinician with experience in treating HCV
8. Education and counseling about avoidance of alcohol and medications toxic to the liver and the risk of transmission
9. Post-exposure follow-up for HCV at weeks 4, 12, and 24

Major Outcomes Considered

- Rate of transmission of human immunodeficiency virus (HIV), or hepatitis B virus (HBV) or hepatitis C virus (HCV) from an occupational exposure
- Efficacy of post-exposure prophylaxis (PEP) in reducing risk of transmission
- Risk of toxicity or other adverse effects from medications used for PEP

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

MEDLINE was searched through July 2012, using appropriate key words. Because there are no randomized controlled studies of this subject, the committee conducted its own review of evidence, including animal studies, mathematical and experimental models, and case reports. Centers for Disease Control and Prevention reports from 1982 until 2012 were reviewed, as were models of transmission risk, to determine information to consider. The committee also reviewed medication efficacy and tolerability reports.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes

III. Expert opinion

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines. These guidelines have also been compared with recommendations published by the Centers for Disease Control and Prevention (CDC) (see Appendix B of the original guideline document).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Because randomized, placebo-controlled clinical trials of post-exposure prophylaxis (PEP) in humans have not been conducted and are not feasible to design, the New York State Department of Health (NYSDOH) guidelines are based on existing published studies, best practice evidence, and the considered opinion of the expert clinicians in the field of adult human immunodeficiency virus (HIV) medicine who comprise the Medical Care Criteria Committee. Expert opinion was frequently used to arrive at recommendations as the PEP literature leaves many questions unanswered or poorly studied.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Effective management of post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) and hepatitis B and C virus in health care workers
- Reduction in risk of transmission of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) after occupational exposure

Potential Harms

- Medications used for post-exposure prophylaxis have risks of toxicity. Please refer to Appendix A of the original guideline document for information on toxicity, dose adjustments, and use in pregnancy for specific antiretroviral (ARV) drugs.
- Although birth defects and adverse effects on human fetuses have generally not been associated with the currently available ARV agents, exposure of a fetus to ARV agents during pregnancy carries a theoretical risk of teratogenicity.

Contraindications

Contraindications

Antiretroviral Drugs to Avoid as Post-Exposure Prophylaxis (PEP) Components

- *Efavirenz*: Although efavirenz is considered a preferred agent for treatment of chronic human immunodeficiency virus (HIV) infection, it is not recommended as part of an initial PEP regimen for several reasons: 1) central nervous system (CNS) side effects are common, complicating the need to provide a first dose at any time of the day; 2) CNS side effects may impair work after the initial and subsequent doses; 3) efavirenz should be avoided in pregnant women, women intending to become pregnant, or women of childbearing potential who are not using effective contraception; and 4) substantial efavirenz resistance continues to be found in community HIV isolates. If efavirenz is used in women of childbearing potential, a pregnancy test should be obtained before initiation and the woman should be counseled about the use of effective contraception while taking efavirenz (see Appendix A in the original guideline document for additional information).
- *Nevirapine* is contraindicated for use in PEP due to the potential for severe hepatotoxicity.
- *Abacavir* should not be used due to the potential for hypersensitivity reactions.
- *Stavudine* and *Didanosine* should not be used due to the possibility of toxicities.

- *Nelfinavir* and *Indinavir* are generally poorly tolerated.
- *CCR5 co-receptor antagonists* should not be used due to lack of activity against potential CXCR4 tropic virus.
- *Rilpivirine* and *Etravirine* have not been commonly used in PEP.

Drugs to Avoid during Pregnancy

- Efavirenz
- Nevirapine
- Combination of stavudine and didanosine
- Unboosted indinavir in the second or third trimester

Qualifying Statements

Qualifying Statements

- When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.
- The New York State Department of Health (NYSDOH) recommendations differ from those published by the Centers for Disease Control and Prevention (CDC) (see Appendix B in the original guideline document). The guidelines of this committee stress simplicity and tolerability in the approach to post-exposure prophylaxis (PEP), recommending a potent but very well tolerated first-line triple therapy for all significant exposures. Recommended second choice regimens are potent and include the best tolerated boosted protease inhibitors.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers, and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC), and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Clinical Algorithm

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2012 Oct. 39 p. [39 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

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Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Medical Care Criteria Committee

Composition of Group That Authored the Guideline

Committee Chair: Judith A Aberg, MD, New York University School of Medicine, New York, New York

Committee Vice-Chair: Samuel T Merrick, MD, New York-Presbyterian Hospital, Weill Cornell Medical Center, New York, New York

Members: Bruce D Agins, MD, MPH, New York State Department of Health AIDS Institute, New York, New York; Barbara Chaffee, MD, MPH, United Health Services, Binghamton, New York; Steven M Fine, MD, PhD, University of Rochester Medical Center, Rochester, New York; Barbara E Johnston, MD, Mount Sinai Comprehensive Health Program-Downtown, New York, New York; Jessica E Justman, MD, Mailman School of Public Health, Columbia University, New York, New York; Jason M Leider, MD, PhD, North Bronx Healthcare Network of Jacobi and North Central Bronx Hospitals, Bronx, New York; Joseph P McGowan, MD, FACP, North Shore University Hospital, Manhasset, New York; Rona M Vail, MD, Callen-Lorde Community Health Center, New York, New York; Barry S Zingman, MD, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, New York

AIDS Institute Staff Liaison: Demetre C Daskalakis, MD, Bellevue Hospital, NYU Langone Medical Center, New York, New York

AIDS Institute Staff Physicians: Charles J Gonzalez, MD, New York State Department of Health AIDS Institute, New York, New York; Cheryl A Smith, MD, New York State Department of Health AIDS Institute, New York, New York

Department of Veterans Affairs Medical Center Liaison: Sheldon T Brown, MD, James J Peters Veteran Affairs Medical Center, Bronx, New York

Medical Society of the State of New York Liaison: William Valenti, MD, FIDSA, University of Rochester School of Medicine, Rochester, New York

New York City Department of Health and Mental Hygiene Liaison: Blayne Cutler, MD, PhD, New York City Department of Health and Mental Hygiene,, Long Island City, New York

New York City Health and Hospitals Corporation Liaison: Joseph R Masci, MD, Elmhurst Hospital Center, Elmhurst, New York

New York State Department of Corrections Liaisons: Douglas G Fish, MD, , Albany Medical College, Albany, New York: Carl J Koenigsmann, MD, New York State Department of Correctional Services, Albany, New York

Pharmacy Advisory Committee Liaison: John M Conry, PharmD, BCPS, AAHIVP, Saint John's University, Queens, New York

HIV Quality of Care Advisory Committee Liaison: Peter G Gordon, MD,, Columbia University College of Physicians and Surgeons, New York, New York

Principal Investigator: John G Bartlett, MD, The Johns Hopkins University, Baltimore, Maryland

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following occupational exposure. New York

(NY): New York State Department of Health; 2010 May. 59 p. [19 references]

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site .

Availability of Companion Documents

The following are available as appendices in the original guideline document :

- Appendix A: antiretroviral drugs.
- Appendix B: occupational exposure to HIV: comparison of NYSDOH and CDC Recommendations.
- Appendix C: post-exposure management: employer issues and responsibilities.
- Appendix D: logistic regression analysis of risk factors for HIV infection after percutaneous exposure to HIV-infected blood.
- Appendix E: interpreting results of testing for antibody to hepatitis C virus.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on March 18, 2004. This NGC summary was updated by ECRI on January 11, 2005. This NGC summary was updated by ECRI Institute on September 19, 2007. This NGC summary was updated by ECRI Institute on June 27, 2008 and November 10, 2010. This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisory on Statins and HIV or Hepatitis C drugs. This summary was updated up ECRI Institute on February 20, 2013.

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